



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0013]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sanitary Transportation of Human and Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0773. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Sanitary Transportation of Human and Animal Food--21 CFR Part 1, Subpart O

This information collection supports FDA regulations regarding the sanitary transportation of human and animal food. The regulations are intended to focus on preventing food safety problems throughout the food chain and were issued under the Sanitary Food Transportation Act of 2005 (2005 SFTA), and the FDA Food Safety Modernization Act, enacted in 2011. The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), in part, by creating section 416 (21 U.S.C. 350e), which directs us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416 of the FD&C Act also directs that we prescribe appropriate human and animal food transportation practice requirements relating to: (1) sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping.

In addition, the 2005 SFTA created section 402(i) of the FD&C Act (21 U.S.C. 342(i)), which provides that food that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulations issued under section 416 is adulterated and section 301(hh) of the FD&C Act (21 U.S.C. 331(hh)), which prohibits the failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the regulations issued under section 416 of the FD&C Act.

The 2005 SFTA also amended section 703 of the FD&C Act (21 U.S.C. 373) by providing that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by FDA, permit the officer or employee, at reasonable times, to have access to and to copy all records that are required to be kept under the regulations issued under section 416 of the FD&C Act.

Accordingly, we issued regulations in 21 CFR part 1, subpart O (21 CFR 1.900 through 1.934) that establish requirements for the sanitary transportation of human and animal food, as well as prescribe procedures for respondents who wish to request a waiver for any requirement. For additional information regarding Agency implementation of the 2005 SFTA, visit our website at <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/sanitation-transportation-guidance-documents-regulatory-information>.

In the *Federal Register* of February 24, 2022 (87 FR 10369), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the information collection topics solicited.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1.912; Record retention	1,502,032	1	1,502,032	0.083 (5 minutes)	124,669

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate an annual recordkeeping burden of 124,669, which assumes 1,502,032 workers will spend an average of 5 minutes on activities related to the record retention requirements under § 1.912. We expect these activities will likely include documenting procedures and training, as well as sanitary transportation operations and specification requirements.

Table 2.--Estimated Annual Reporting Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1.914; Waiver petitions	2	1	2	24	48

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate one waiver petition from each of two firms will be submitted and respondents will spend 24 hours to prepare and submit the petition to FDA.

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
1.908; Disclosure of sanitary specifications; operating temperature conditions	226	1	226	0.5833 (~35 minutes)	132

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Finally, we estimate an annual third-party disclosure burden of 132 hours, assuming each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under § 1.908.

Based on an evaluation of the information collection, we have made no adjustments to our burden estimate.

Dated: June 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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